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Translation

PCT/JP2003/016655

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 3132WO0P	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2003/016655	International filing date (*day/month/year*) 25 December 2003 (25.12.2003)	Priority date (*day/month/year*) 26 December 2002 (26.12.2002)
International Patent Classification (IPC) or national classification and IPC C07K 14/47, C12N 15/12, C12P 21/02, C12Q 1/68, C07K 16/18, A01K 67/027, C12N 5/10, G01N 33/15, 33/50, A61K 31/711, 38/17, 39/395, A61P 35/00		
Applicant TAKEDA CHEMICAL INDUSTRIES, LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☒ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) 1 Diskette, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I — Basis of the report
- ☐ Box No. II — Priority
- ☒ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

Date of submission of the demand 27 January 2004 (27.01.2004)	Date of completion of this report 31 May 2004 (31.05.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☒ in computer readable form

   c. time of filing/furnishing

   ☐ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purpose of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

** If item 4 in Box No. I applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 20, 28, 36-42

because:

☒ the said international application, or the said claims Nos. 20, 37-40 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

See supplemental sheet

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 28, 36, 41, 42 are so unclear that no meaningful opinion could be formed *(specify)*:

See supplemental sheet

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 20, 28, 36-42.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ see Supplemental Box for further details.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III. 1.

The subject matter of claims 20 and 37-40 relates to methods for treatment as well as diagnostic methods. Thus, this International Preliminary Examining Authority is not required to carry out international preliminary examination on this subject matter under the provisions of PCT Article 34(4)(a)(i) and PCT Rule 67.1(iv).

It is completely unknown what specific compounds are involved in the scope of the substances inhibiting the expression of a peptide, a gene, etc. as set forth in claims 28, 36, 41 and 42 and what are not. Thus, the above claims are described in an extremely unclear manner. Such being the case, no meaningful opinion can be presented concerning the novelty, inventive step and industrial applicability of the inventions set forth in the above claims and claims depending thereon.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2,6-7,25-27,29-30,33-35	YES
	Claims	1,3-5,8-19,21-24,31-32	NO
Inventive step (IS)	Claims		YES
	Claims	1-19, 21-27, 29-35	NO
Industrial applicability (IA)	Claims	1-19, 21-27, 29-35	YES
	Claims		NO

2. Citations and explanations

Document 1: WO 00/12708 A2 (Genentech, Inc.)
Document 2: WO 01/68848 A2 (Genentech, Inc.)
Document 3: WO 01/77137 A1 (Human Genome Sciences, Inc.)
Document 4: WO 01/36440 A1 (Human Genome Sciences, Inc.)
Document 5: WO 02/52005 A1 (Kazusa DNA Research Institute Foundation)
Document 6: WO 00/78961 A1 (Genentech, Inc.)
Document 7: WO 02/46465 A2 (Oxford Biomedica Limited)
Document 8: WO 02/06329 A2 (Curagen Co.)

Claims 1, 3 to 5, 8 to 19, 21 to 24, 31 and 32

Documents 1 to 4 set forth a protein (PRO1480 (documents 1 and 2), HKAHL26 (document 3) and protein coded by gene No. 1 (document 4)) having 99% homogeneity with an amino acid sequence represented by sequence numbers 4, 7 or 10 of this application, and indicate that this protein is made to serve as a coding polynucleotide, recombinant vector, transformant or drug/diagnostic product. Documents 1 to 4 also disclose a screening method for inhibiting compounds (see document 1, claims, pages 183 to 185, fig. 141 and 142, sequence table sequence numbers 252 and 253; document 2, claims 22 and 23, pages 32 and 132, fig. 453 and 454, sequence table sequence numbers 453 and 454; document 3, claims; page 150;

sequence table sequence number 1271; document 4, claims, pages 9 to 13 and 94 to 102, sequence table sequence numbers 11 and 64).

The amino acid sequence of the proteins disclosed in these documents effectively contains the same amino acid sequence as the amino acid sequence represented by sequence numbers 4, 7 or 10 of this application, therefore the inventions set forth in claims 1, 3 to 5, 8 to 19, 21 to 24 and 31 to 34 of this application cannot be distinguished from the inventions set forth in documents 1 to 4.

Claims 2, 6 and 7, 25 to 27, 29 and 30, 33 to 35

Documents 1 to 4 set forth a protein (PRO1480 (documents 1 and 2), HKAHL26 (document 3) and protein coded by gene No. 1 (document 4)) having 99% homogeneity with an amino acid sequence represented by sequence numbers 4, 7 or 10 of this application, and indicate that this protein is made to serve as a coding polynucleotide, recombinant vector, transformant or drug/diagnostic product. Documents 1 to 4 also disclose a screening method for inhibiting compounds (see document 1, claims, pages 183 to 185, fig. 141 and 142, sequence table sequence numbers 252 and 253; document 2, claims 22 and 23, pages 32 and 132, fig. 453 and 454, sequence table sequence numbers 453 and 454; document 3, claims, page 150, sequence table sequence number 1271; document 4, claims; pages 9 to 13 and 94 to 102; sequence table sequence numbers 11 and 64).

Documents 1 to 4 also indicate that said protein or polynucleotide are involved with cancer and apotosis (see document 1, page 22; document 2, page 132; document 3, page 150; document 4, pages 11, 94 to 102, especially code H0486 and H0574).

The amino acid sequence of the proteins disclosed in

these documents effectively contain the same amino acid sequence as the amino acid sequence represented by sequence numbers 4, 7 or 10 of this application, therefore it would be easy for a person skilled in the art to conceive of attempting to manufacture a cancer-related drug based on the protein or polynucleotide set forth in documents 1 to 4.

Therefore the inventions set forth in claims 25 to 27, 29, 30, and 33 to 35 cannot be distinguished from the inventions set forth in documents 1 to 4.

In addition, documents 1 to 4 also set forth polynucleotides that code disclosed cancer-related proteins, therefore it would be easy for a person skilled in the art to conceive of carrying out screening using these polynucleotides to obtain the polynucleotide which codes the polypeptide having a specific sequence set forth in the invention of this application. Moreover, it would not be difficult for a person skilled in the art to obtain a polynucleotide with high sequence homogeneity.

It would therefore be easy for a person skilled in the art to conceive of the inventions set forth in claims 2, 6 and 7 of this application in the light of documents 1 to 4.

Claims 1, 3 to 5, 8 to 19, 21 to 24, 31 and 32

Documents 5 to 8 set forth a protein having 99% homogeneity with an amino acid sequence represented by sequence numbers 4, 7 or 10 of this application (pj01678 (document 5), PRO1480 (document 6), sequence numbers 91 and 92 (document 7), NOV 7 (document 8)), and indicate that this protein is made to serve as a coding polynucleotide, recombinant vector, transformant or drug/diagnostic product. Documents 5 to 8 also disclose a screening method for inhibiting compounds (see document 5, claims, pages 12 to 18, sequence table sequence number 31;

document 6, claims, pages 180 to 182 and 355, fig. 141 and 142, sequence table sequence numbers 252 and 253; document 7, claims, page 256, sequence table sequence numbers 91 and 92; document 8, claims, pages 51 to 58, sequence table sequence numbers 17 and 18).

The amino acid sequence of the proteins disclosed in these documents effectively contain the same amino acid sequence as the amino acid sequence represented by sequence numbers 4, 7 or 10 of this application, therefore the inventions set forth in claims 1, 3 to 5, 8 to 19, 21 to 24 and 31 to 32 of this application cannot be distinguished from the inventions set forth in documents 5 to 8.